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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,055	10/30/2000	Aziz Asghar	1103326-0590	3456

7590 08/19/2005

White & Case
Patent Department
1155 Avenue of the Americas
New York, NY 10036-2787

EXAMINER	
LUKTON, DAVID	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/381,055	ASGHAR ET AL.	
	Examiner	Art Unit	
	David Lukton	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-19* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 and 13-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/6/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Pursuant to the response filed 6/6/05, no claim has been amended, cancelled, or added. Claims 9-19 remain pending.

Applicants have requested a change in the elected group to Group I, which currently consists of claims 9 and 13-19. Applicants' requested is granted; the previous species election (the NMDA receptor antagonist is remacemide) remains in force.

Claims 9 and 13-19 are examined in this Office action. The previously imposed prior art rejections are withdrawn herewith.

The abbreviation **IBD** is used hereinbelow to denote "irritable bowel syndrome".

✧

The following is a quotation of the first paragraph of 35 U.S.C. §112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 13-19 are rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants have shown that compounds falling within the scope of formula I are effective to reduce the visceromotor response to colorectal distension. However, applicants have made no attempt to relate this finding to the claimed

invention. The claimed invention is treatment of IBD. Applicants have not shown that colorectal distension invariably accompanies IBD, or that it usually accompanies IBD. And even if it is true that colorectal distension invariably accompanies IBD, there is no evidence of record that reducing the magnitude of colorectal distension in any way provides therapeutic relief to patients suffering from IBD. Applicants have made no assertion (or provided any evidence) that the underlying inflammation is affected one way or another by the compounds.

As stated in *Ex parte Forman* (230 USPQ 546, 1986) and *In re Wands* (8 USPQ2d 1400, Fed. Cir., 1988) the factors to consider in evaluating the need (or absence of need) for "undue experimentation" are the following: quantity of experimentation necessary, amount of direction or guidance presented, presence or absence of working examples, nature of the invention, state of the prior art, relative skill of those in that art, predictability or unpredictability of the art, and breadth of the claims. There is no evidence that the skilled gastroenterologist would believe that colorectal distension qualifies as a suitable model for IBD, or that attenuating the visceromotor response to colorectal distension provides any sort of benefit to the patient suffering from IBD. There are no "working examples" which show benefit to the mammal stricken with IBD.

In accordance with the foregoing, "undue experimentation" would be required to practice the claimed invention.

✦

Claims 9 and 13-19 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- The claims are indefinite as to the manifestations of a successful treatment. Normally the term "treatment" means that the symptoms of a disease are mitigated so that the patient "feels better" to at least a perceptible degree. Thus, in general a claim drawn to a method of treating irritable bowel syndrome would mean that inflammation of the gut is perceptibly mitigated. Not so in the instant case. Applicants have chosen a rather arcane measure of success, and one which affects neither the inflammation itself nor the well being of the patient. As they stand, the claims encompass the possibility of reducing the inflammation with which the patient is suffering. This particular rejection asserts indefiniteness, rather than lack of enablement, but the foregoing explanation is provided because it is relevant. In any case, as indicated, the claims are indefinite as to the manifestations of a successful treatment. Perhaps one option would be the following:

  to *A method of treating irritable bowel syndrome comprising administering a patient in need thereof an NMDA receptor antagonist for a time and under conditions effective to attenuate the visceromotor response to colorectal distension.*

  (The examiner makes no representation that the foregoing claim language will necessarily overcome the §112, first paragraph rejection)

- Claim 17 is not properly dependent on claim 14. Applicants are requested to explain why it is that they believe this compound falls within the scope of the genus of formula I.

✧

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as

set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 9 and 13 are rejected under 35 U.S.C. §103 as being unpatentable over Alam S. (*Canadian Journal of Anaesthesia* (1996 Apr) **43** (4) 408-13 in view of Martin, D. (*Neuropharmacology* **10**, 999-1003, 1985).

Alam discloses that ketamine exhibits a significant effect in the colorectal distention test. Alam does not disclose that if a compound exhibits an effect in the colorectal distention test, it will be effective to treat IBD. Alam also does not disclose that ketamine is a non-competitive antagonist of the NMDA receptor. Martin discloses that ketamine is a non-competitive antagonist of the NMDA receptor.

The examiner asserts that the gastroenterologist of ordinary skill would believe that if a compound exhibits an effect in the colorectal distention test, it will be effective to treat IBD. And as conveyed by Martin, ketamine is a non-

competitive antagonist of the NMDA receptor. Accordingly, it would have been obvious that the ketamine disclosed in Alam is an NMDA receptor antagonist, and that it is effective to treat IBD.

Thus, the claims are rendered obvious.

✧

Claims 9 and 14 are rejected under 35 U.S.C. §103 as being unpatentable over Schneider (USP 6,048,543).

Schneider discloses (e.g., col 19, line 10) that glycine can be used to treat inflammatory bowel diseases.

The gastroenterologist of ordinary skill would regard IBD as being within the scope of "inflammatory bowel diseases". In addition, the drug metabolism specialist of ordinary skill would regard glycine as a metabolite of the compound of formula I (claim 14).

Thus, the claims are rendered obvious.

✧

WO 93/22279 was stricken from the IDS because of the absence of a translation. However, the abstract has been considered, as indicated on the accompanying PTO-892.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached at (571)272-0974. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800